M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: February 8, 2000

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: An Overview of OGD

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: The Immediate Office of the Director

Presented for: 1999 Fall Technical Workshop

Date Presented: 10/18/99

Presented by: Gary J. Buehler

Number of Pages: 19

M. Lamb

Attachment

90S-0308

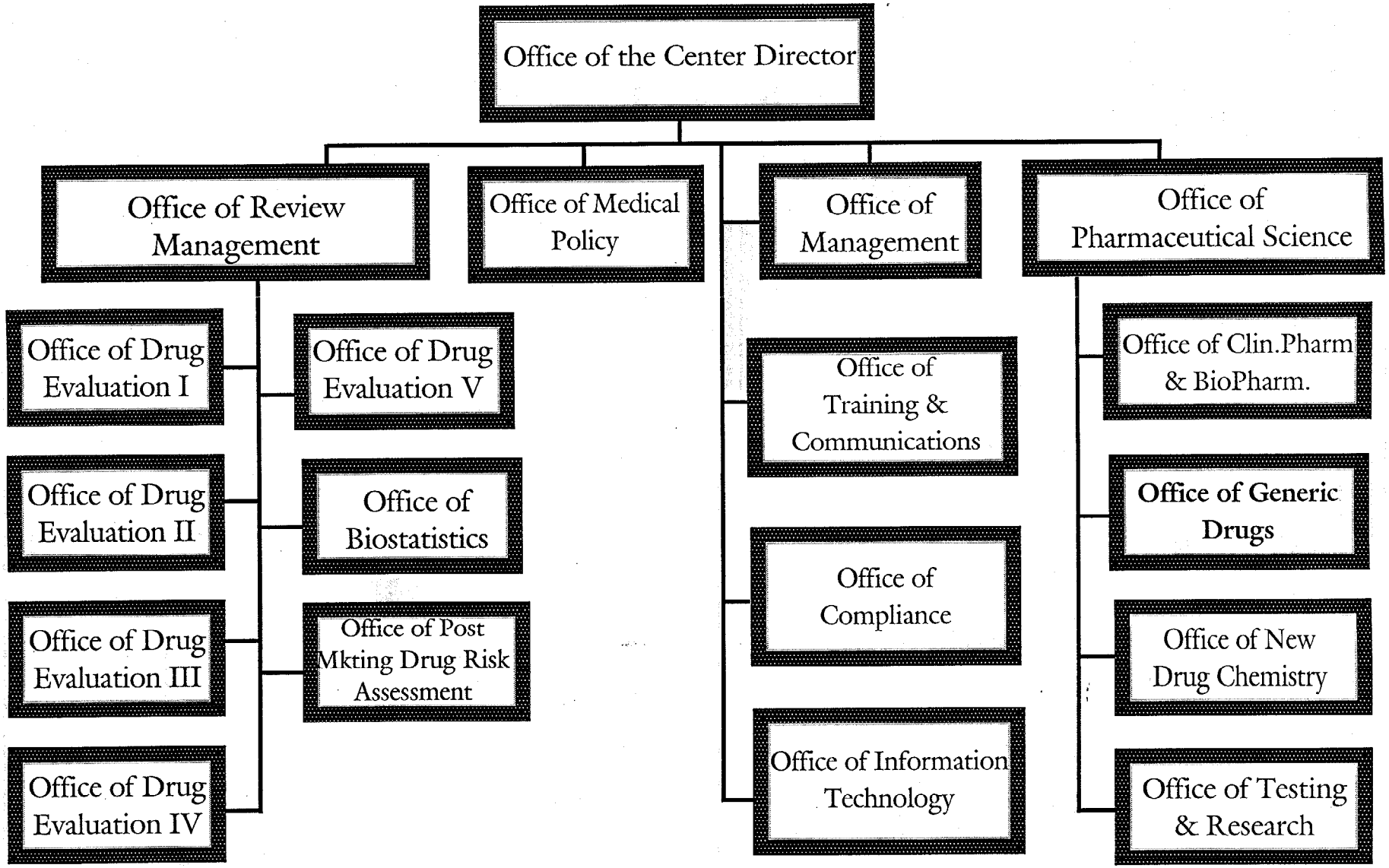
M654

AN OVERVIEW OF OGD

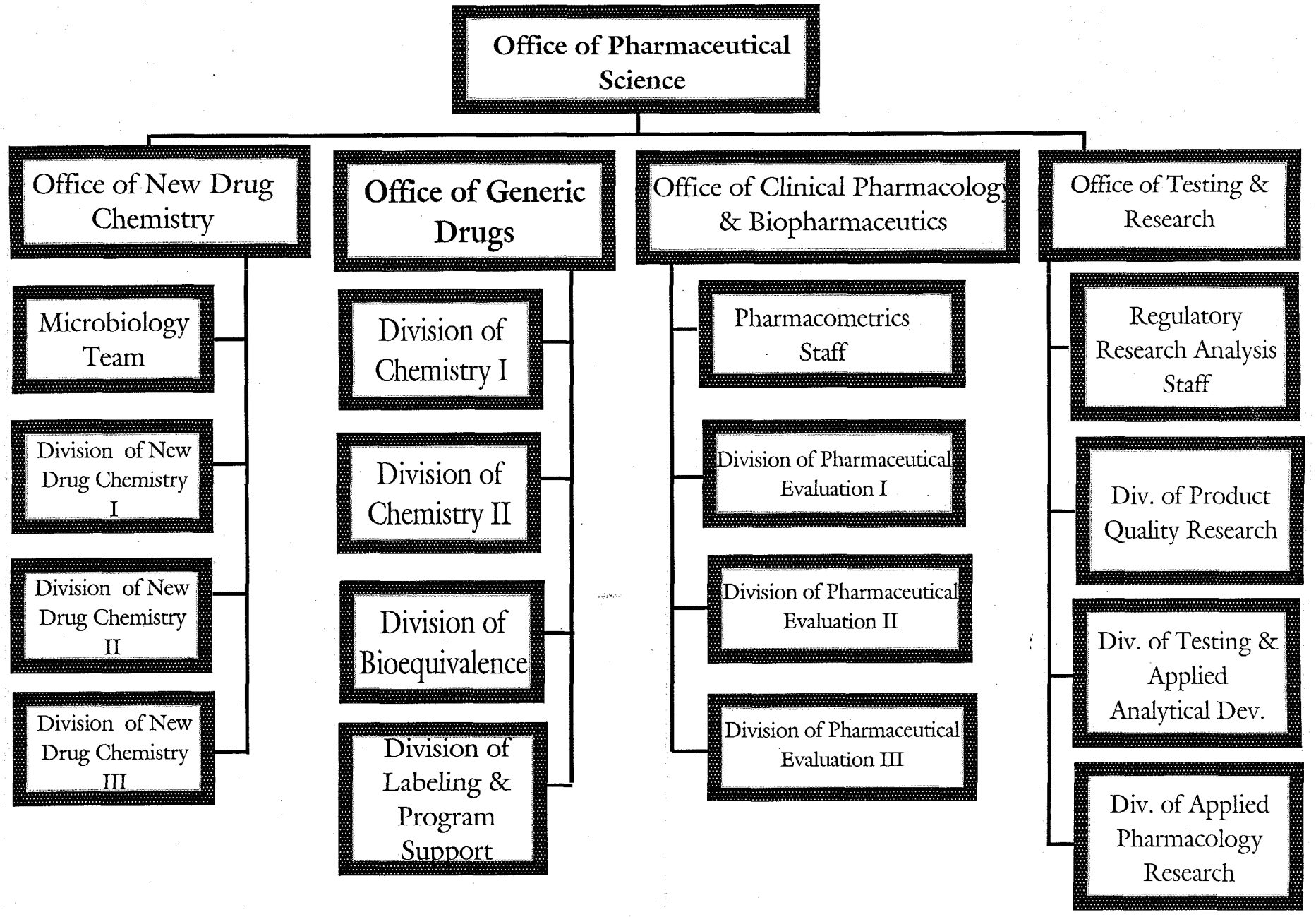
THE IMMEDIATE OFFICE OF THE DIRECTOR

Gary J. Buehler
Deputy Director
Office of Generic Drugs
October 18, 1999

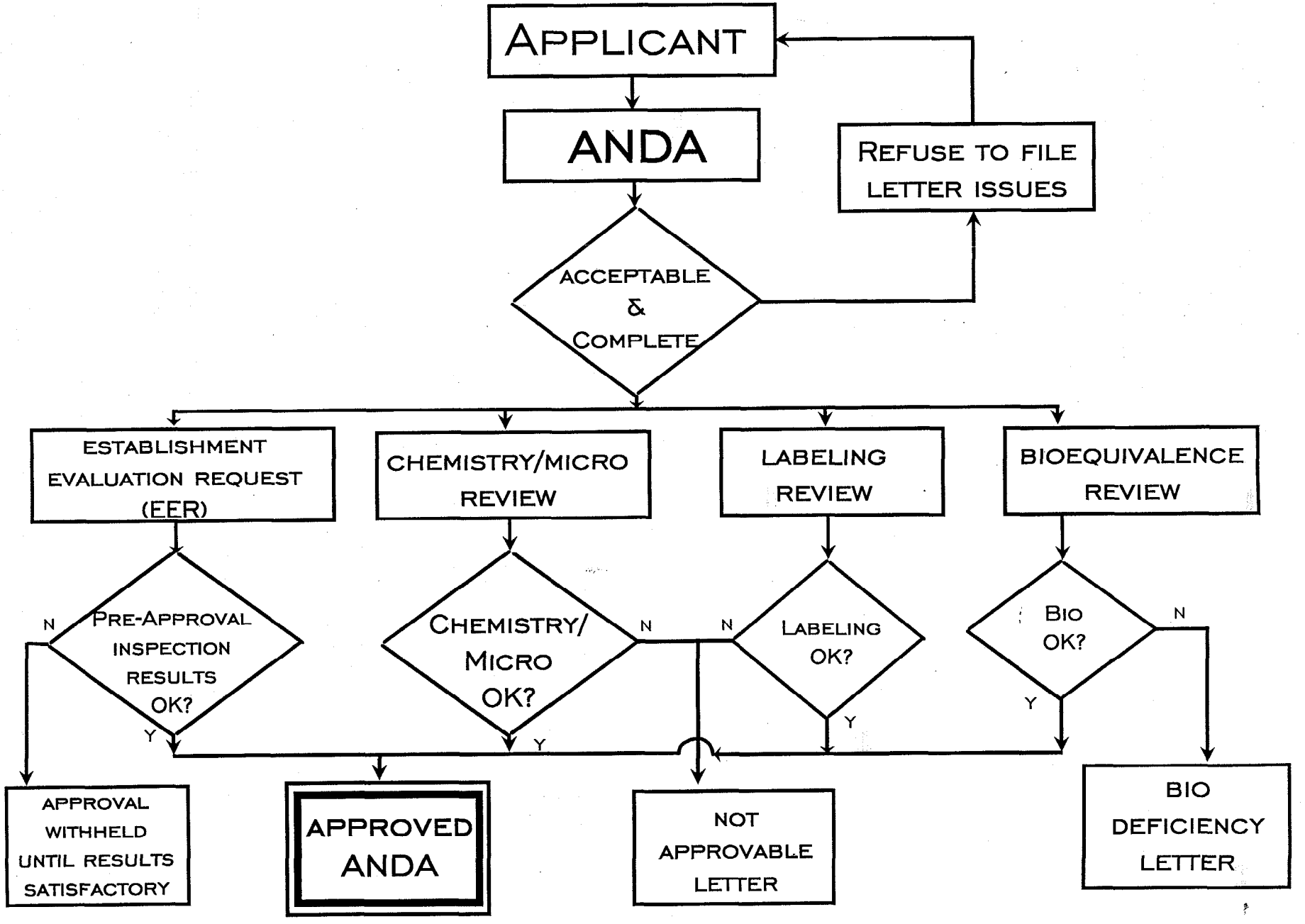
Center for Drug Evaluation and Research



Center for Drug Evaluation and Research



Generic Drug Review Process

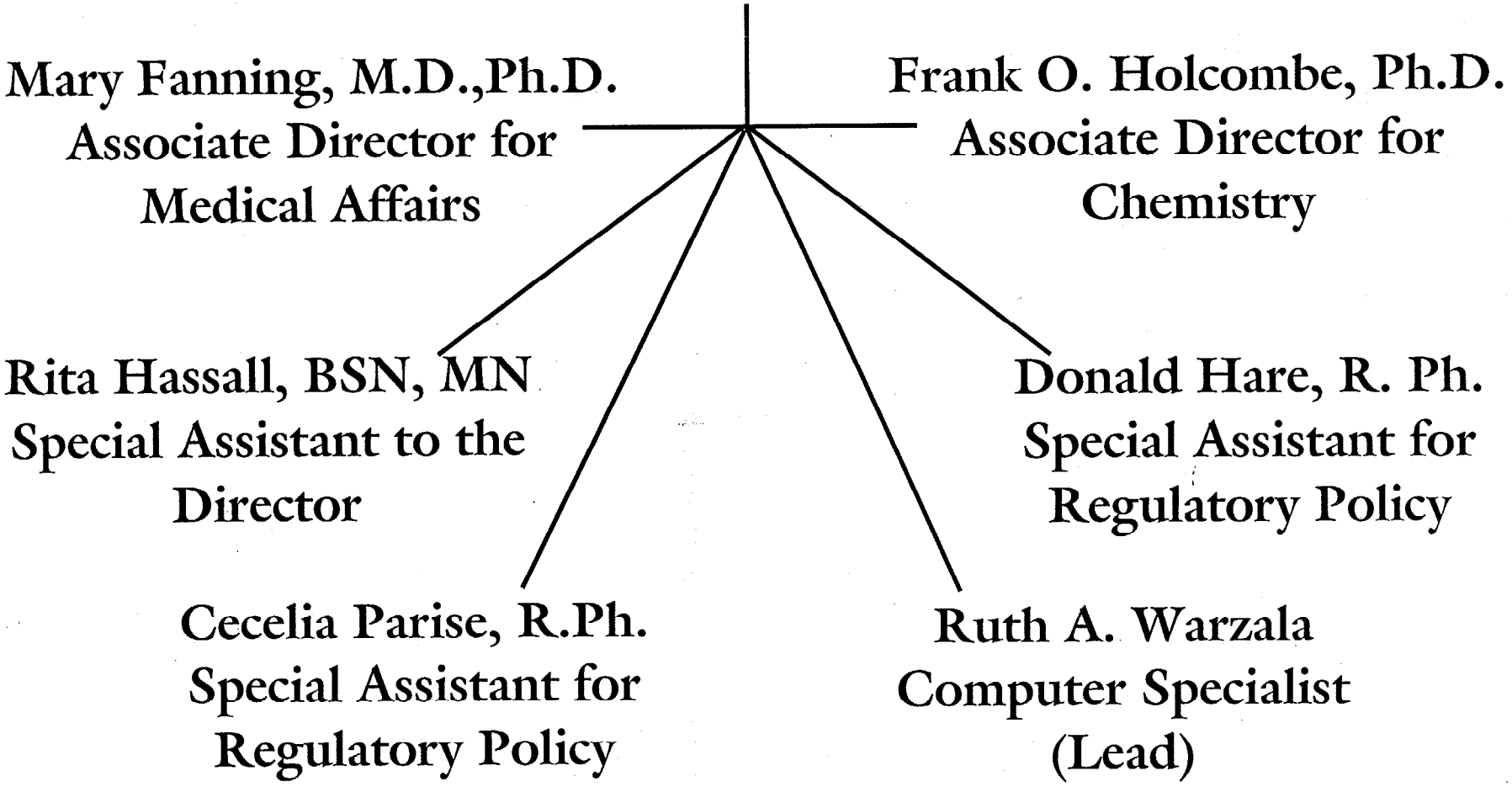


Office of Generic Drugs

Immediate Office

Doug Sporn, Director

Gary Buehler, Deputy Director



Mary Fanning, M.D., Ph.D.
Associate Director for Medical Affairs

- Review InVivo Bioequivalence Studies
- Guidance Preparation
- Review Inactive Ingredient Issues
- Supervise Micro Function
- Perform Health Hazard Evaluation
- Evaluate Adverse Event Reports

Frank O. Holcombe, Ph.D.

Associate Director for Chemistry

- OGD Application Audit/Office Quality Control for CMC Review
- Co-Chair for CMCCC
- Provide Recommendations to Office Director on CMC Issues

Rita Hassall, BSN, MN

Special Assistant to the Director

- Controlled Correspondence - CMC/Labeling/Immed. Office Issues
- MAPPs and Guidances
- Doug's Day-to-Day Activities (Calls, Emails, Presentations
- Office Action Items
- Conjugated Estrogens
- Lawsuits

Donald Hare, R.Ph.

Special Assistant for Regulatory Policy

- Hatch/Waxman Exclusivity Issues
- Orange Book
- 505 (b)(2) Applications
- Inactive Ingredients
- Liaison to States
- Office Historian
- Lawsuits

Cecelia Parise, R.Ph.

Special Assistant for Regulatory Policy

- Controlled Correspondence - Bioequivalence
- Citizen Petitions
- Suitability Petitions
- PET
- 180 Day Exclusivity
- Lawsuits

Ruth A. Warzala

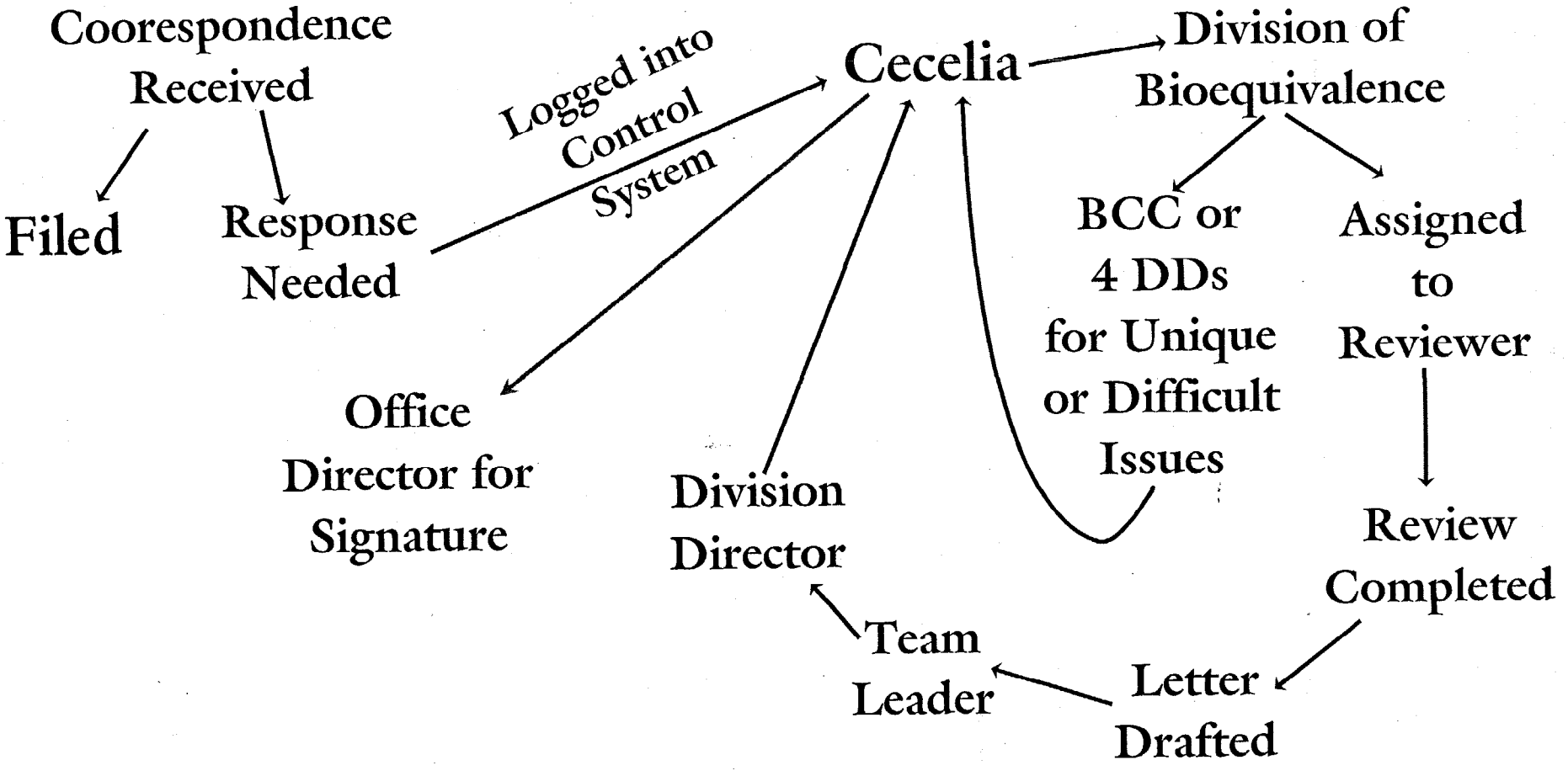
Computer Specialist (Lead)

- ANDA Electronic Submissions Project Manager
- ANDA COMIS Steering Committee Facilitator
- Develop IT Special Projects & Procurements
- OPS IT Committee Representative
- Ad hoc Computer Support & Reporting

Controlled Correspondence

Bioequivalence Issues

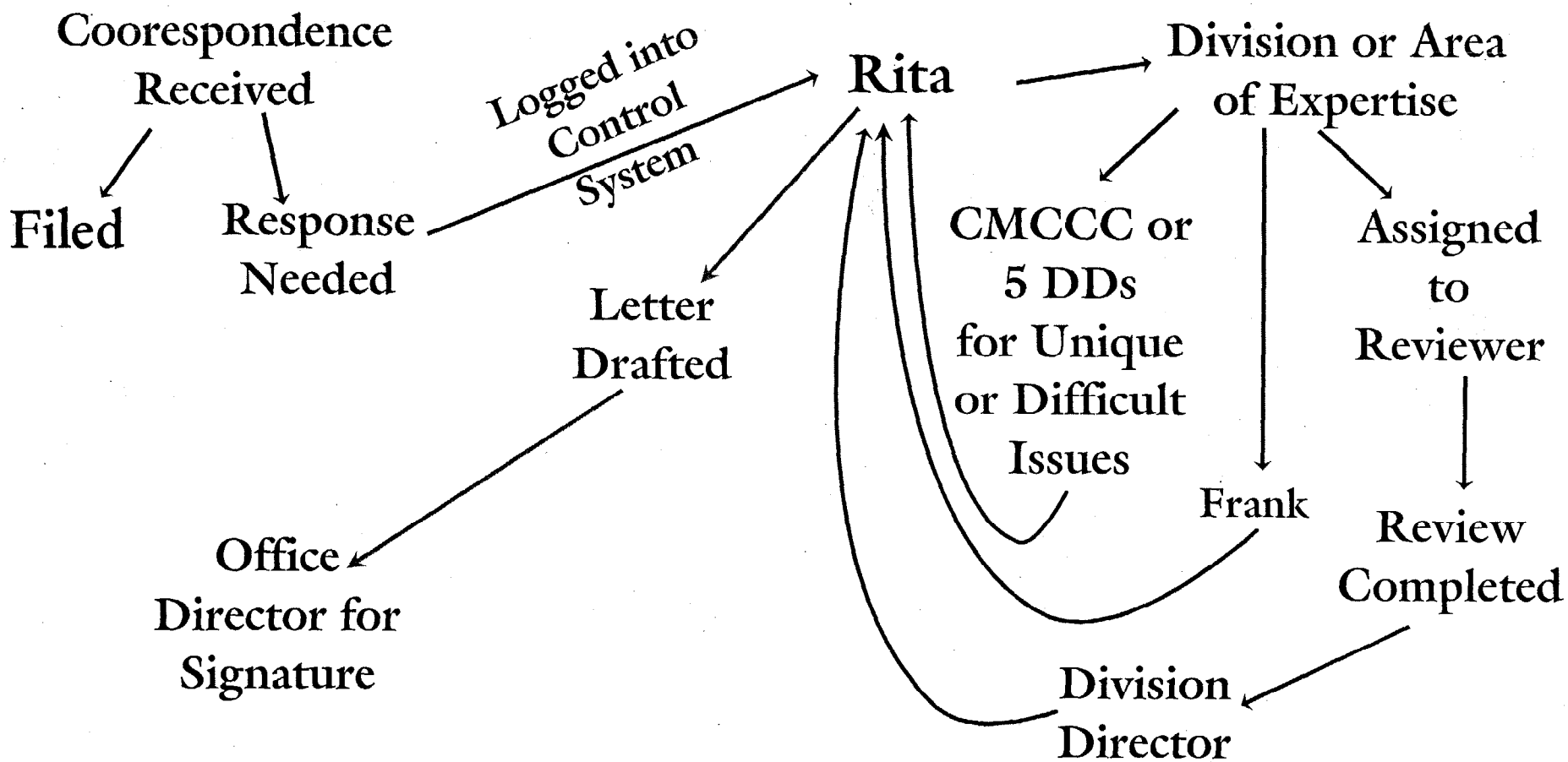
Cecelia Parise, R.Ph.



Controlled Correspondence

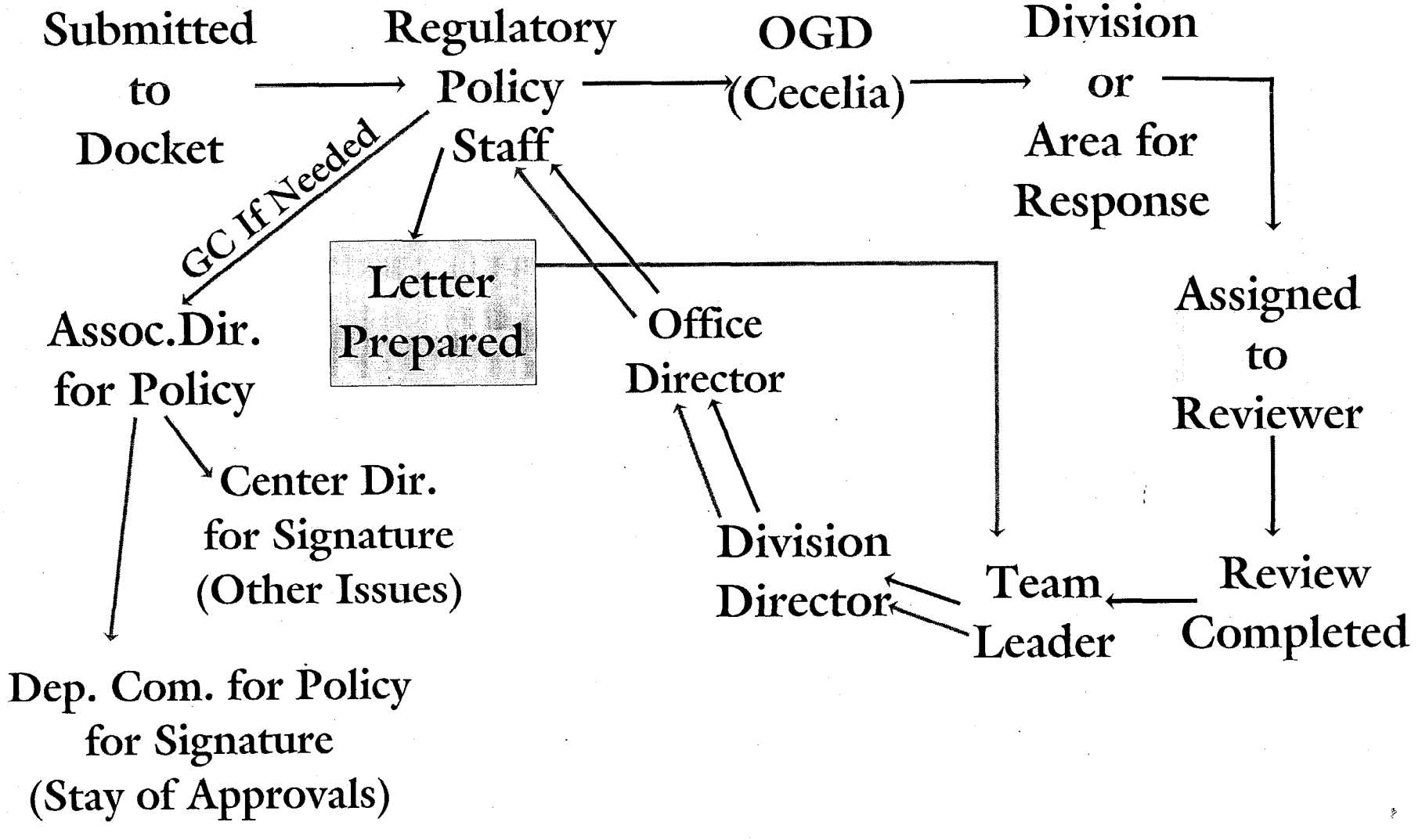
CMC/Labeling/Immediate Office Issues

Rita Hassall, BSN, MN



Citizen Petitions

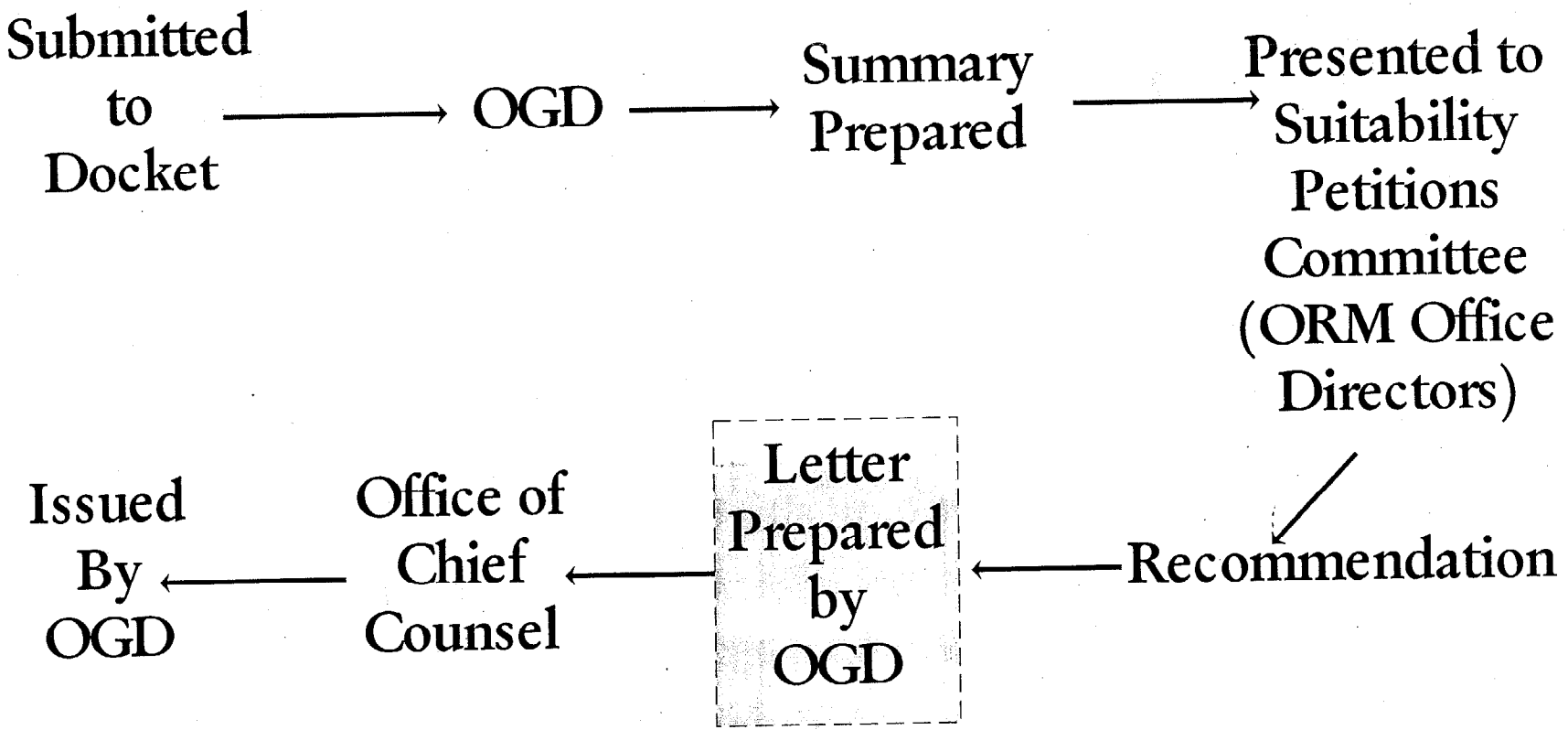
Cecelia Parise, R.Ph.



Suitability Petitions

Cecelia Parise, R.Ph.

Gregg Davis, R. Ph.



Impact of the Pediatric Rule on Suitability Petitions

- Petitionable Changes Affected:
  - Change in Dosage Form
  - Change in Route of Administration
  - Change in Active Ingredient in a Combination Drug

- Changes in Strength are <u>Not</u> Affected by the Pediatric Rule

Impact of the Pediatric Rule on Suitability Petitions

- Waivers of Pediatric Studies May Be Granted If the Proposed Product:
  - Does not represent a meaningful therapeutic benefit over existing treatments

  AND
  - Is not likely to be used in a substantial number of pediatric patients

- If a Waiver of Pediatric Studies is Denied, the Suitability Petition will be Denied.

Immediate Office

Phone: 301-827-5845

FAX: 301-594-0183

What Does the BOSS do?